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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,934	07/24/2003	Kenneth David Reginald Setchell	CHM-013M1	9470

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1626	
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09/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,934	SETCHELL ET AL.	
	Examiner	Art Unit	
	Susannah Chung	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-19 and 27-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *12-19 and 45* is/are allowed.

6)☒ Claim(s) *1,2,4,5,27-44 and 46-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 4-11, 12-19, 27-49 are pending in the instant application. Claims 3 and 20-26 are canceled. Claims 6-11, 27-43, and 46-49 are withdrawn as non-elected subject matter.

Response to RCE after Final

Applicant's RCE, amendment to the claims and remarks filed on 8/27/2007 are acknowledged.

Claims 1-2, 4-5, 12-17, 19, and 44-45 were rejected under 103 as obvious over the prior art of Gorbach and Miller. Applicants argue that the equol in the prior art is different from the instantly claimed equol because the prior art equol is a natural product, which is usually not found in the racemic form, and did not have a process of making the equol. This is found persuasive and the 103 rejection is withdrawn.

Claims 1-2, 4-5, 12-19, and 44-45 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 6-11, 27-43, and 46-49, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 7/25/2006 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory

double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims, for the reasons describe below.

As stated in MPEP 2164.01(a), "there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

The factors to be considered when determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, were described in In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) as:

1. the nature of the invention;
2. the breadth of the claims;
3. the state of the prior art;
4. the relative skill of those in the art;
5. the predictability or unpredictability of the art;

6. the amount of direction or guidance presented [by the inventor];

7. the presence or absence of working examples; and

8. the quantity of experimentation necessary [to make and/or use the invention].

The eight Wands factors are applied to Claims 27-43 of the present invention below:

(1) The Nature of the Invention

Claims 27-43 are directed to a method of delivering S-equol to a mammal to prevent or treat a disease or associated condition, comprising administering to the mammal a composition comprising S-equol or a conjugated analog thereof.

(2) The Breadth of the claims

Claims 27-43 will be give its broadest reasonable interpretation. The applicable rule for interpreting the claims is that "each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description." See MPEP 2163(II)(1), citing In re Morris, 127 F.3d 1048, 1053-1054; 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). In view of this rule, Claims 27-30 and 43, which do not specify a disorder will be interpreted to treat and prevent all possible disorders. Claims 31-32, which provide more specific classes of diseases will be interpreted to encompass all possible disorders within that class of diseases as well as treat and prevent those disorders.

(3) The state of the prior art

It was known in the art at the time of this application that equol is a naturally occurring product that can be used to treat specific diseases in menopausal women. (See US Pat. Nos. 6,716,424 B1 and 7,025,998 B2). The state of the art at the time of this application was that no

single compound could treat all the diseases as instantly claimed, i.e. osteoporosis (claim 36), cancer (claim 37), dementia (claim 39), inflammatory conditions (claim 40), etc...

(4) The relative skill of those in the art

The level of skill in the art (pharmaceutical chemists, physicians) would be high.

(5) The predictability or unpredictability of the art

It is noted that the pharmaceutical art generally is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement varies inversely with the degree of unpredictability in the factors involved. In re Fisher, 427 F.2d 833, 839. Therefore, the more unpredictable an area, the more specific enablement is needed in order to satisfy the statute. Added to the unpredictability of the art itself is the question whether supplementing the in vivo production of s-equol (specification page 25, lines 1-6) could be reliably and predictably extrapolated to in vivo activity in patients with the particular diseases claimed resulting in treatment of that disease. There is no absolute predictability, even in view of the high level of skill in the art.

(6) The amount of direction or guidance presented (by the inventor)

The specification on pages 25-29 discusses the treatment of disease by administering S-equol. The specification on pages 29-31 discusses the treatment of disease by administering S-equol. It is stated that the delivery of equol will result in in vivo production of S-equol, but there is no data, i.e. assay data, patient population data, to support this assertion.

(7) The presence or absence of working examples

As noted in the previous section, the specification discloses the general role of equol, but there are no working examples, such as in vivo or in vitro studies of the role equol plays in the treatment of specific diseases.

(8) The quantity of experimentation necessary (to make and/or use the invention)

Given the absence of direction or guidance (or working examples) in the specification for the role of equol in the treatment of a disorder it would cause a skilled artisan an undue amount of experimentation to practice this invention to determine which patients with which diseases would benefit from which of the many claimed compounds within the scope of the invention with a reasonable expectation of success.

Note term "prevent" is an absolute definition which means to stop from occurring and thus requires a higher standard for enablement than does "treat." Accordingly it is suggested that the term "prevent" be omitted from the claim language to overcome this part of the enablement rejection.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-11, and 46-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The "commercial products," "article of commerce," and "food supplement" comprising a non-racemic mixture of S-equol and R-equol is not defined in the specification so as to know the types of commercial products, articles of commerce and food supplements that are included and/or excluded by the term. This leaves s-

equol alone, which is known in the art (Alvira et al., Chem. Phy., Vol. 240, Is. 1-2, 1999, pages 101-108, which teaches S-equol). Therefore, the specification lacks adequate support for Claims 1, 2, 4-11.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-11, and 46-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 2, 4-11 are indefinite for the reasons set forth above under 35 U.S.C. 112, first paragraph. Claims 1, 2, 4-11 drawn to "commercial products," "articles of commerce," and "food supplement" are not defined in the claims so as to know the metes and bounds of the claims. Therefore, the claims are indefinite.

Conclusion

The closest prior art of record is Alvira et al., Chem. Phy., Vol. 240, Is. 1-2, 1999, pages 101-108, which teaches S-equol, but does not teach the use of S-equol in a composition.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLC

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Date: 11 September 2007